



VIRGINIA DEPARTMENT OF ENVIRONMENTAL QUALITY

NORTHERN REGIONAL OFFICE
13901 Crown Court, Woodbridge, Virginia 22193
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Matthew J. Strickler
Secretary of Natural Resources

David K. Paylor
Director

Thomas A. Faha
Regional Director

**STATE AIR POLLUTION CONTROL BOARD
ENFORCEMENT ACTION - ORDER BY CONSENT
ISSUED TO
GRANULES PHARMACEUTICALS, INC.
FOR
THE GRANULES PHARMACEUTICALS FACILITY
Registration No. 72351**

SECTION A: Purpose

This is a Consent Order issued under the authority of Va. Code §§ 10.1-1309 and -1316, between the State Air Pollution Control Board and Granules Pharmaceuticals, Inc., regarding the Granules Pharmaceuticals Facility for the purpose of resolving certain violations of the Virginia Air Pollution Control Law and the applicable permit and regulations.

SECTION B: Definitions

Unless the context clearly indicates otherwise, the following words and terms have the meaning assigned to them below:

1. "Board" means the State Air Pollution Control Board, a permanent citizens' board of the Commonwealth of Virginia, as described in Va. Code §§ 10.1-1184 and -1301.
2. "Department" or "DEQ" means the Department of Environmental Quality, an agency of the Commonwealth of Virginia, as described in Va. Code § 10.1-1183.

3. "Director" means the Director of the Department of Environmental Quality, as described in Va. Code § 10.1-1185.
4. "Facility" means the Granules Pharmaceuticals Facility, located at 3701 Concorde Parkway in Chantilly, Virginia.
5. "FCE" means Full Compliance Evaluation.
6. "Granules" means Granules Pharmaceuticals, Inc. a corporation authorized to do business in Virginia and its affiliates, partners, and subsidiaries. Granules Pharmaceuticals, Inc. is a "person" within the meaning of Va. Code § 10.1-1300.
7. "Notice of Violation" or "NOV" means a type of Notice of Alleged Violation under Va. Code § 10.1-1309.
8. "NRO" means the Northern Regional Office of DEQ, located in Woodbridge, Virginia.
9. "Order" means this document, also known as a "Consent Order" or "Order by Consent," a type of Special Order under the Virginia Air Pollution Control Law.
10. "Permit" means a minor New Source Review permit to install, operate, and modify certain pharmaceutical microsphere coating equipment, issued under the Virginia Air Pollution Control Law and the Regulations to Fuisz Technologies Ltd. on May 6, 1998. DEQ received a change of ownership form on January 7, 2016, which stated that Granules Pharmaceuticals, Inc. had taken over ownership of the Facility.
11. "Regulations" or "Regulations for the Control and Abatement of Air Pollution" mean 9 VAC 5 chapters 10 through 80.
12. "Va. Code" means the Code of Virginia (1950), as amended.
13. "VAC" means the Virginia Administrative Code.
14. "Virginia Air Pollution Control Law" means Chapter 13 (§ 10.1-1300 *et seq.*) of Title 10.1 of the Va. Code.

SECTION C: Findings of Fact and Conclusions of Law

1. Granules owns and operates the Facility in Chantilly, Virginia. The Facility is a pharmaceutical microsphere coating operation.
2. On May 31, 2018, DEQ conducted an FCE at the Facility. DEQ staff observed the following:

- a. Three pharmaceutical coating machines; Glatt GPCG 3 (R&D), Labocoat-1, and Labcoat-3 machines were observed in operation at the Facility. This equipment was not listed in the equipment list of the Permit.
 - b. Granules staff were unable to provide maximum hourly Volatile Organic Compound throughput of each of the permitted coating machines (Glatt GPCG 60 (with 60kg insert and 250 kg insert) and Glatt GPCG 3 (GMP)) to DEQ.
3. 9 VAC 5-80-1120.A states that no owner or other person shall begin actual construction of, or operate, any new stationary source or any project subject to this article without first obtaining from the board a permit under the provisions of this article. The owner may not construct or operate the stationary source or project contrary to the terms and conditions of that permit.
4. Permit Condition 6 states that the volatile organic compound (VOC) throughput for the Pharmaceutical microsphere coating machines shall not exceed 275 pounds per hour. The hourly VOC throughput for the facility represents the combined capacity of the spray nozzles of each machine.
5. Permit Condition 11 states in relevant part that the permittee shall maintain records of all emission data and operating parameters necessary to demonstrate compliance with this permit.
6. On August 20, 2018, based on the observations noted by DEQ staff during the May 31, 2018, FCE, the Department issued Notice of Violation No. ANRO000993 to Granules Pharmaceuticals, Inc. for the violations described in paragraphs C(2) through C(5) above.
7. Based on observations noted by DEQ staff during the May 31, 2018 FCE, the Board concludes that Granules has violated Permit Conditions 6, and 11, and 9 VAC 5-80-1120.A as described in paragraphs C(2) through C(5), above.
8. DEQ met with representatives of Granules on September 18, 2018 to discuss the Notice of Violation and corrective action.
9. On September 21, 2018, Granules provided VOC throughput documentation to DEQ which showed that the permitted equipment was being operated within permitted VOC limits.
10. In order for Granules to return to compliance, DEQ staff and representatives of Granules, have agreed to the Schedule of Compliance, which is incorporated as Appendix A of this Order.

SECTION D: Agreement and Order

Accordingly, by virtue of the authority granted it in Va. Code §§ 10.1-1309 and -1316, the Board orders Granules Pharmaceuticals, Inc., and Granules Pharmaceuticals, Inc. agrees

1. Perform the actions described in Appendix A of this Order; and
2. Pay a civil charge of \$15,120.77 within 30 days of the effective date of the Order in settlement of the violations cited in this Order.

Payment shall be made by check, certified check, money order or cashier's check payable to the "Treasurer of Virginia," and delivered to:

Receipts Control
Department of Environmental Quality
Post Office Box 1104
Richmond, Virginia 23218

Granules Pharmaceuticals, Inc. shall include its Federal Employer Identification Number (FEIN) with the civil charge payment and shall indicate that the payment is being made in accordance with the requirements of this Order for deposit into the Virginia Environmental Emergency Response Fund (VEERF). If the Department has to refer collection of moneys due under this Order to the Department of Law, Granules Pharmaceuticals, Inc. shall be liable for attorneys' fees of 30% of the amount outstanding.

SECTION E: Administrative Provisions

1. The Board may modify, rewrite, or amend this Order with the consent of Granules Pharmaceuticals, Inc. for good cause shown by Granules Pharmaceuticals, Inc. or on its own motion pursuant to the Administrative Process Act, Va. Code § 2.2-4000 *et seq.*, after notice and opportunity to be heard.
2. This Order addresses and resolves only those violations specifically identified in Section C of this Order. This Order shall not preclude the Board or the Director from taking any action authorized by law, including but not limited to: (1) taking any action authorized by law regarding any additional, subsequent, or subsequently discovered violations; (2) seeking subsequent remediation of the facility; or (3) taking subsequent action to enforce the Order.
3. For purposes of this Order and subsequent actions with respect to this Order only, Granules Pharmaceuticals, Inc. admits the jurisdictional allegations, findings of fact, and conclusions of law contained herein.
4. Granules Pharmaceuticals, Inc. consents to venue in the Circuit Court of the City of Richmond for any civil action taken to enforce the terms of this Order.

5. Granules Pharmaceuticals, Inc. declares it has received fair and due process under the Administrative Process Act and the Virginia Air Pollution Control Law and it waives the right to any hearing or other administrative proceeding authorized or required by law or regulation, and to any judicial review of any issue of fact or law contained herein. Nothing herein shall be construed as a waiver of the right to any administrative proceeding for, or to judicial review of, any action taken by the Board to modify, rewrite, amend, or enforce this Order.
6. Failure by Granules Pharmaceuticals, Inc. to comply with any of the terms of this Order shall constitute a violation of an order of the Board. Nothing herein shall waive the initiation of appropriate enforcement actions or the issuance of additional orders as appropriate by the Board or the Director as a result of such violations. Nothing herein shall affect appropriate enforcement actions by any other federal, state, or local regulatory authority.
7. If any provision of this Order is found to be unenforceable for any reason, the remainder of the Order shall remain in full force and effect.
8. Granules Pharmaceuticals, Inc. shall be responsible for failure to comply with any of the terms and conditions of this Order unless compliance is made impossible by earthquake, flood, other acts of God, war, strike, or such other unforeseeable circumstances beyond its control and not due to a lack of good faith or diligence on its part. Granules Pharmaceuticals, Inc. shall demonstrate that such circumstances were beyond its control and not due to a lack of good faith or diligence on its part. Granules Pharmaceuticals, Inc. shall notify the DEQ Regional Director verbally within 24 hours and in writing within three business days when circumstances are anticipated to occur, are occurring, or have occurred that may delay compliance or cause noncompliance with any requirement of the Order. Such notice shall set forth:
 - a. the reasons for the delay or noncompliance;
 - b. the projected duration of any such delay or noncompliance;
 - c. the measures taken and to be taken to prevent or minimize such delay or noncompliance; and
 - d. the timetable by which such measures will be implemented and the date full compliance will be achieved.

Failure to so notify the Regional Director verbally within 24 hours and in writing within three business days, of learning of any condition above, which the parties intend to assert will result in the impossibility of compliance, shall constitute a waiver of any claim to inability to comply with a requirement of this Order.

9. This Order is binding on the parties hereto and any successors in interest, designees and assigns, jointly and severally.
10. This Order shall become effective upon execution by both the Director or his designee and Granules Pharmaceuticals, Inc.. Nevertheless, Granules Pharmaceuticals, Inc. agrees to be bound by any compliance date which precedes the effective date of this Order.
11. This Order shall continue in effect until:
 - a. The Director or his designee terminates the Order after Granules Pharmaceuticals, Inc. has completed all of the requirements of the Order;
 - b. Granules Pharmaceuticals, Inc. petitions the Director or his designee to terminate the Order after it has completed all of the requirements of the Order and the Director or his designee approves the termination of the Order; or
 - c. the Director or Board terminates the Order in his or its sole discretion upon 30 days' written notice to Granules Pharmaceuticals, Inc..

Termination of this Order, or any obligation imposed in this Order, shall not operate to relieve Granules Pharmaceuticals, Inc., from its obligation to comply with any statute, regulation, permit condition, other order, certificate, certification, standard, or requirement otherwise applicable.

12. Any plans, reports, schedules or specifications attached hereto or submitted by Granules Pharmaceuticals, Inc. and approved by the Department pursuant to this Order are incorporated into this Order. Any non-compliance with such approved documents shall be considered a violation of this Order.
13. The undersigned representative of Granules Pharmaceuticals, Inc. certifies that he or she is a responsible official authorized to enter into the terms and conditions of this Order and to execute and legally bind Granules Pharmaceuticals, Inc. to this document. Any documents to be submitted pursuant to this Order shall also be submitted by a responsible official of Granules Pharmaceuticals, Inc..
14. This Order constitutes the entire agreement and understanding of the parties concerning settlement of the violations identified in Section C of this Order, and there are no representations, warranties, covenants, terms or conditions agreed upon between the parties other than those expressed in this Order.
15. By its signature below, Granules Pharmaceuticals, Inc. voluntarily agrees to the issuance of this Order.

And it is so ORDERED this 2nd day of April, 2019.



Thomas A. Faha, Regional Director
Department of Environmental Quality

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Granules Pharmaceuticals, Inc. voluntarily agrees to the issuance of this Order.

Date: 03/26/2019 By: Maudan, PRESIDENT - ACCOUNTING & FINANCE
(Person) (Title)
[Granules Pharmaceuticals, Inc.]

Commonwealth of Virginia
City/County of Fairfax

The foregoing document was signed and acknowledged before me this 26 day of March, 2019, by KAMAL L. MANDAN who is PRESIDENT - ACCOUNTING & FIN of Granules Pharmaceuticals, Inc. on behalf of the corporation.

JAMILLAH BEY
NOTARY PUBLIC
REGISTRATION # 7667291
COMMONWEALTH OF VIRGINIA
MY COMMISSION EXPIRES
JANUARY 31, 2020

[Signature]
Notary Public

7667291

Registration No.

My commission expires: 1/31/20

Notary seal:



APPENDIX A
SCHEDULE OF COMPLIANCE

Granules Pharmaceuticals, Inc. shall:

1. Submit a Form 7 to DEQ within 30 days of execution of this Order. Once submitted, Granules Pharmaceuticals, Inc. shall respond to any requests for information from DEQ permitting staff within the timeframe specified by DEQ permitting staff.

Mandy

03/26/2019